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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/782,627	REED ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *2-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed February 18, 2004, is acknowledged and has been entered. Claim 1 has been canceled.

2. Claims 2-34 are pending in the application and are currently subject to restriction.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1. Claims 2-5, insofar as the claims are drawn to a nucleic acid molecule, or complement thereof, comprising at least 20 contiguous nucleotides of the polynucleotide sequence set forth in SEQ ID NO: 1, which encodes a polypeptide having the amino acid sequence set forth in SEQ ID NO: 2, classified in class 536, subclass 23.5.

Group 2. Claims 2-5 and 6, insofar as the claims are drawn to a nucleic acid molecule, or complement thereof, comprising at least 20 contiguous nucleotides of the polynucleotide sequence set forth in SEQ ID NO: 3, which encodes a polypeptide having the amino acid sequence set forth in SEQ ID NO: 4, classified in class 536, subclass 23.5.

Group 3. Claims 2-5 and 7, insofar as the claims are drawn to a nucleic acid molecule, or complement thereof, comprising at least 20 contiguous nucleotides of the polynucleotide sequence set forth in SEQ ID NO: 5, which encodes a polypeptide having the amino acid sequence set forth in SEQ ID NO: 6, classified in class 536, subclass 23.5.

Group 4. Claims 2-5 and 8, insofar as the claims are drawn to a nucleic acid molecule, or complement thereof, comprising at least 20 contiguous nucleotides of the polynucleotide sequence set forth in SEQ ID NO: 7, which encodes a polypeptide having the amino acid sequence set forth in SEQ ID NO: 8, classified in class 536, subclass 23.5.

Group 5. Claims 2-5 and 9, insofar as the claims are drawn to a nucleic acid molecule, or complement thereof, comprising at least 20 contiguous nucleotides of the polynucleotide sequence set forth in SEQ ID NO: 9, which encodes a polypeptide having the amino acid sequence set forth in SEQ ID NO: 10, classified in class 536, subclass 23.5.

Group 6. Claims 2-5 and 10, insofar as the claims are drawn to a nucleic acid molecule, or complement thereof, comprising at least 20 contiguous nucleotides of the polynucleotide sequence set forth in SEQ ID NO: 19, which encodes a polypeptide having the amino acid sequence set forth in SEQ ID NO: 20, classified in class 536, subclass 23.5.

Group 7. Claims 2-5 and 11, insofar as the claims are drawn to a nucleic acid molecule, or complement thereof, comprising at least 20 contiguous nucleotides of the polynucleotide sequence set forth in SEQ ID NO: 21, which encodes a polypeptide having the amino acid sequence set forth in SEQ ID NO: 22, classified in class 536, subclass 23.5.

Group 8. Claims 2-5 and 12, insofar as the claims are drawn to a nucleic acid molecule, or complement thereof, comprising at least 20 contiguous nucleotides of the polynucleotide sequence set forth in SEQ ID NO: 23, which encodes a polypeptide having the amino acid sequence set forth in SEQ ID NO: 24, classified in class 536, subclass 23.5.

Group 9. Claims 13-16 and 26, insofar as the claims are drawn to a protein comprising the amino acid sequence of SEQ ID NO: 2 or a fragment, derivative or mimetic thereof, and a composition comprising said protein, classified, for example, in class 530, subclass 350.

Group 10. Claims 13, 14, 17, and 26, insofar as the claims are drawn to a protein comprising the amino acid sequence of SEQ ID NO: 4 or a fragment, derivative or mimetic thereof, and a composition comprising said protein, classified, for example, in class 530, subclass 350.

Group 11. Claim 13, 14 and 26, insofar as the claim is drawn to a protein comprising the amino acid sequence of SEQ ID NO: 6 or a fragment, derivative or mimetic

thereof, and a composition comprising said protein, classified, for example, in class 530, subclass 350.

Group 12. Claim 13, 14 and 26, insofar as the claim is drawn to a protein comprising the amino acid sequence of SEQ ID NO: 8 or a fragment, derivative or mimetic thereof, and a composition comprising said protein, classified, for example, in class 530, subclass 350.

Group 13. Claim 13, 14 and 26, insofar as the claim is drawn to a protein comprising the amino acid sequence of SEQ ID NO: 10 or a fragment, derivative or mimetic thereof, and a composition comprising said protein, classified, for example, in class 530, subclass 350.

Group 14. Claims 13, 14, 18, and 26, insofar as the claims are drawn to a protein comprising the amino acid sequence of SEQ ID NO: 20 or a fragment thereof, and a composition comprising said protein, classified, for example, in class 530, subclass 350.

Group 15. Claims 13, 14, 19, and 26, insofar as the claims are drawn to a protein comprising the amino acid sequence of SEQ ID NO: 22 or a fragment thereof, and a composition comprising said protein, classified, for example, in class 530, subclass 350.

Group 16. Claims 13, 14, 20-23, and 26, insofar as the claims are drawn to a protein comprising the amino acid sequence of SEQ ID NO: 24 or a fragment thereof, and a composition comprising said protein, classified, for example, in class 530, subclass 350.

Group 17. Claim 25, insofar as the claim is drawn to a method of modulating tumor cell proliferation, cell migration, metastasis, and steroid hormone function, said method comprising administering a nucleic acid molecule, or complement thereof, comprising at least 20 contiguous nucleotides of the polynucleotide sequence set forth in SEQ ID NO: 1, classified, for example, in class 514, subclass 44.

Group 18. Claim 25, insofar as the claim is drawn to a method of modulating tumor cell proliferation, cell migration, metastasis, and steroid hormone function, said

method comprising administering a nucleic acid molecule, or complement thereof, comprising at least 20 contiguous nucleotides of the polynucleotide sequence set forth in SEQ ID NO: 3, classified, for example, in class 514, subclass 44.

Group 19. Claim 25, insofar as the claim is drawn to a method of modulating tumor cell proliferation, cell migration, metastasis, and steroid hormone function, said method comprising administering a nucleic acid molecule, or complement thereof, comprising at least 20 contiguous nucleotides of the polynucleotide sequence set forth in SEQ ID NO: 5, classified, for example, in class 514, subclass 44.

Group 20. Claim 25, insofar as the claim is drawn to a method of modulating tumor cell proliferation, cell migration, metastasis, and steroid hormone function, said method comprising administering a nucleic acid molecule, or complement thereof, comprising at least 20 contiguous nucleotides of the polynucleotide sequence set forth in SEQ ID NO: 7, classified, for example, in class 514, subclass 44.

Group 21. Claim 25, insofar as the claim is drawn to a method of modulating tumor cell proliferation, cell migration, metastasis, and steroid hormone function, said method comprising administering a nucleic acid molecule, or complement thereof, comprising at least 20 contiguous nucleotides of the polynucleotide sequence set forth in SEQ ID NO: 9, classified, for example, in class 514, subclass 44.

Group 22. Claim 25, insofar as the claim is drawn to a method of modulating tumor cell proliferation, cell migration, metastasis, and steroid hormone function, said method comprising administering a nucleic acid molecule, or complement thereof, comprising at least 20 contiguous nucleotides of the polynucleotide sequence set forth in SEQ ID NO: 19, classified, for example, in class 514, subclass 44.

Group 23. Claim 25, insofar as the claim is drawn to a method of modulating tumor cell proliferation, cell migration, metastasis, and steroid hormone function, said

method comprising administering a nucleic acid molecule, or complement thereof, comprising at least 20 contiguous nucleotides of the polynucleotide sequence set forth in SEQ ID NO: 21, classified, for example, in class 514, subclass 44.

Group 24. Claim 25, insofar as the claim is drawn to a method of modulating tumor cell proliferation, cell migration, metastasis, and steroid hormone function, said method comprising administering a nucleic acid molecule, or complement thereof, comprising at least 20 contiguous nucleotides of the polynucleotide sequence set forth in SEQ ID NO: 23, classified, for example, in class 514, subclass 44.

Group 25. Claims 27-29, insofar as the claims are drawn to a method of modulating tumor cell proliferation, said method comprising administering a composition comprising a protein having the amino acid sequence of SEQ ID NO: 2, classified, for example, in class 514, subclass 2.

Group 26. Claims 27-29, insofar as the claims are drawn to a method of modulating tumor cell proliferation, said method comprising administering a composition comprising a protein having the amino acid sequence of SEQ ID NO: 4, classified, for example, in class 514, subclass 2.

Group 27. Claims 27-29, insofar as the claims are drawn to a method of modulating tumor cell proliferation, said method comprising administering a composition comprising a protein having the amino acid sequence of SEQ ID NO: 6, classified, for example, in class 514, subclass 2.

Group 28. Claims 27-29, insofar as the claims are drawn to a method of modulating tumor cell proliferation, said method comprising administering a composition comprising a protein having the amino acid sequence of SEQ ID NO: 8, classified, for example, in class 514, subclass 2.

Group 29. Claims 27-29, insofar as the claims are drawn to a method of modulating tumor cell proliferation, said method comprising administering a composition comprising a protein having the amino acid sequence of SEQ ID NO: 10, classified, for example, in class 514, subclass 2.

Group 30. Claims 27-29, insofar as the claims are drawn to a method of modulating tumor cell proliferation, said method comprising administering a composition comprising a protein having the amino acid sequence of SEQ ID NO: 20, classified, for example, in class 514, subclass 2.

Group 31. Claims 27-29, insofar as the claims are drawn to a method of modulating tumor cell proliferation, said method comprising administering a composition comprising a protein having the amino acid sequence of SEQ ID NO: 22, classified, for example, in class 514, subclass 2.

Group 32. Claims 27-29, insofar as the claims are drawn to a method of modulating tumor cell proliferation, said method comprising administering a composition comprising a protein having the amino acid sequence of SEQ ID NO: 24, classified, for example, in class 514, subclass 2.

Group 33. Claims 30 and 31, insofar as the claims are drawn to an antibody that specifically binds to a protein having the amino acid sequence of SEQ ID NO: 2, classified, for example, in class 530, subclass 387.9.

Group 34. Claims 30 and 31, insofar as the claims are drawn to an antibody that specifically binds to a protein having the amino acid sequence of SEQ ID NO: 4, classified, for example, in class 530, subclass 387.9.

Group 35. Claims 30 and 31, insofar as the claims are drawn to an antibody that specifically binds to a protein having the amino acid sequence of SEQ ID NO: 6, classified, for example, in class 530, subclass 387.9.

Group 36. Claims 30 and 31, insofar as the claims are drawn to an antibody that specifically binds to a protein having the amino acid sequence of SEQ ID NO: 8, classified, for example, in class 530, subclass 387.9.

Group 37. Claims 30 and 31, insofar as the claims are drawn to an antibody that specifically binds to a protein having the amino acid sequence of SEQ ID NO: 10, classified, for example, in class 530, subclass 387.9.

Group 38. Claims 30 and 31, insofar as the claims are drawn to an antibody that specifically binds to a protein having the amino acid sequence of SEQ ID NO: 20, classified, for example, in class 530, subclass 387.9.

Group 39. Claims 30 and 31, insofar as the claims are drawn to an antibody that specifically binds to a protein having the amino acid sequence of SEQ ID NO: 22, classified, for example, in class 530, subclass 387.9.

Group 40. Claims 30 and 31, insofar as the claims are drawn to an antibody that specifically binds to a protein having the amino acid sequence of SEQ ID NO: 24, classified, for example, in class 530, subclass 387.9.

Group 41. Claim 32, insofar as the claim is drawn to a method for detecting the presence of a protein in a sample, said method comprising obtaining a sample and adding to the sample an antibody that specifically binds to a protein having the amino acid sequence of SEQ ID NO: 2, classified, for example, in class 435, subclass 7.1.

Group 42. Claim 32, insofar as the claim is drawn to a method for detecting the presence of a protein in a sample, said method comprising obtaining a sample and adding to the sample an antibody that specifically binds to a protein having the amino acid sequence of SEQ ID NO: 4, classified, for example, in class 435, subclass 7.1.

Group 43. Claim 32, insofar as the claim is drawn to a method for detecting the presence of a protein in a sample, said method comprising obtaining a sample and adding to the sample an antibody that specifically binds to a protein having the amino acid sequence of SEQ ID NO: 6, classified, for example, in class 435, subclass 7.1.

Group 44. Claim 32, insofar as the claim is drawn to a method for detecting the presence of a protein in a sample, said method comprising obtaining a sample and adding to the sample an antibody that specifically binds to a protein having the amino acid sequence of SEQ ID NO: 8, classified, for example, in class 435, subclass 7.1.

Group 45. Claim 32, insofar as the claim is drawn to a method for detecting the presence of a protein in a sample, said method comprising obtaining a sample and adding to the sample an antibody that specifically binds to a protein having the

amino acid sequence of SEQ ID NO: 10, classified, for example, in class 435, subclass 7.1.

Group 46. Claim 32, insofar as the claim is drawn to a method for detecting the presence of a protein in a sample, said method comprising obtaining a sample and adding to the sample an antibody that specifically binds to a protein having the amino acid sequence of SEQ ID NO: 20, classified, for example, in class 435, subclass 7.1.

Group 47. Claim 32, insofar as the claim is drawn to a method for detecting the presence of a protein in a sample, said method comprising obtaining a sample and adding to the sample an antibody that specifically binds to a protein having the amino acid sequence of SEQ ID NO: 22, classified, for example, in class 435, subclass 7.1.

Group 48. Claim 32, insofar as the claim is drawn to a method for detecting the presence of a protein in a sample, said method comprising obtaining a sample and adding to the sample an antibody that specifically binds to a protein having the amino acid sequence of SEQ ID NO: 24, classified, for example, in class 435, subclass 7.1.

Group 49. Claim 33, insofar as the claim is drawn to a method for detecting the presence of nucleic acid molecule encoding a protein in a sample, classified, for example, in class 435, subclass 6.

Group 50. Claim 34, insofar as the claim is drawn to a method of determining risk of metastatic spread of cancer or prognosis of cancer patients, said method comprising determining the level of expression of a protein, classified, for example, in class 436, subclass 501.

4. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups 1-16 and 33-40 are products, whereas the inventions of Groups 17-32 and 41-50 are processes.

The inventions of Groups 1-8 and the inventions of Groups 25-32 and 41-50 are unrelated because the products of Groups 1-8 are not specifically used or otherwise involved in the processes of Groups 25-32 and 41-50.

The inventions of Groups 9-16 and the inventions of Groups 17-24 and 41-50 are unrelated because the products of Groups 9-16 are not specifically used or otherwise involved in the processes of Groups 17-24 and 41-50.

The inventions of Groups 33-40 and the inventions of Groups 17-32, 49, and 50 are unrelated because the products of Groups 33-40 are not specifically used or otherwise involved in the processes of Groups 17-32, 49, and 50.

The inventions of Groups 1-8 and the inventions of Groups 17-24, respectively, are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the nucleic acid molecule can be used in a materially different process of using that product, such as the process of using nucleic acid molecule as a probe to detect the presence in a sample of other nucleic acid molecules that hybridize to the nucleic acid molecule by Northern blot analysis, for example.

The inventions of Groups 1-8 and the inventions of Groups 17-24 have acquired a separate status in the art, as evidenced by their different classifications and/or art-recognized divergence in subject matter, and the search performed in examining claims drawn to a product is a different from the search performed in examining claims drawn to a process using that product. Apart from the searching patent databases using the patent classification of the claimed subject matter, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, the search and considerations necessary in examining the merit of claims of Group 1-8 would not suffice to provide adequate

information regarding the merit of the claims of Group 17-24, and vice versa, since the searches are not the same, nor are they one coextensive in scope and nature. Because different searches would have to be performed to examine the inventions of Groups 1-8 and the inventions of Groups 17-24, respectively, an examination of both would constitute a serious burden.

Since the inventions of Groups 1-8 and the inventions of Groups 17-24, respectively, have been shown to be patentably distinct, and because the examination of both inventions could not be made without serious burden, it is proper to restrict each from the other. See MPEP § 803.

The inventions of Groups 9-16 and the inventions of Groups 25-32, respectively, are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the polypeptide can be used in a materially different process of using that product, such as the process of using polypeptide as an immunogen to produce an antibody that binds to the polypeptide.

The inventions of Groups 9-16 and the inventions of Groups 25-32 have acquired a separate status in the art, as evidenced by their different classifications and/or art-recognized divergence in subject matter, and the search performed in examining claims drawn to a product is a different from the search performed in examining claims drawn to a process using that product. Apart from the searching patent databases using the patent classification of the claimed subject matter, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, the search and considerations necessary in examining the merit of claims of Group 9-16 would not suffice to provide adequate information regarding the merit of the claims of Group 25-32, and vice versa, since the searches are not the same, nor are they one coextensive in scope and nature. Because different searches would have to be performed to examine the inventions of Groups 9-16 and the inventions of Groups 25-32, respectively, an examination of both would constitute a serious burden.

Since the inventions of Groups 9-16 and the inventions of Groups 25-32, respectively, have been shown to be patentably distinct, and because the examination of both inventions could not be made without serious burden, it is proper to restrict each from the other. See MPEP § 803.

The inventions of Groups 33-40 and the inventions of Groups 41-48, respectively, are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the antibody can be used in a materially different process of using that product, such as the process of using the antibody to purify the polypeptide to which the antibody binds by affinity chromatography.

The inventions of Groups 33-40 and the inventions of Groups 41-48 have acquired a separate status in the art, as evidenced by their different classifications and/or art-recognized divergence in subject matter, and the search performed in examining claims drawn to a product is a different from the search performed in examining claims drawn to a process using that product. Apart from the searching patent databases using the patent classification of the claimed subject matter, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, the search and considerations necessary in examining the merit of claims of Group 33-40 would not suffice to provide adequate information regarding the merit of the claims of Group 41-48, and vice versa, since the searches are not the same, nor are they one coextensive in scope and nature. Because different searches would have to be performed to examine the inventions of Groups 33-40 and the inventions of Groups 41-48, respectively, an examination of both would constitute a serious burden.

Since the inventions of Groups 33-40 and the inventions of Groups 41-48, respectively, have been shown to be patentably distinct, and because the examination of both inventions could

not be made without serious burden, it is proper to restrict each from the other. See MPEP § 803.

The inventions of Groups 1-16 and 33-40 are patentably distinct for the following reasons:

The inventions of Groups 1-8 are nucleic acid molecules or compositions thereof; the inventions of Groups 9-16 are c polypeptides or compositions thereof; and the inventions of Groups 33-40 are antibodies.

Polypeptides and polynucleotides are chemically distinct products, since polypeptides are composed of polymers of amino acids, whereas polynucleotides are composed of polymers of nucleotides. Any relationship between a polynucleotide and a polypeptide is dependent upon the information provided by the nucleotide sequence of the polynucleotide, as it corresponds to an "open reading frame" encoding the amino acid sequence of the polypeptide. However, a polypeptide can be produced by means, other than the recombinant means by which a polynucleotide encoding a polypeptide might be used to produce the polypeptide, since a polypeptide can be produced (or isolated) by biochemical means, including, for example, affinity chromatography. In addition, while the polynucleotide might encode the polypeptide, generally, it can also encode another polypeptide using the information provided by an alternative open reading frame; and furthermore, since a polynucleotide can be used as a probe in hybridization-based analyses, the information provided by a polynucleotide can be used isolate different polynucleotides encoding polypeptides, which have amino acid sequences that differ from the amino acid sequence encoded by the disclosed polynucleotide. Consequently, the disclosed relationship between a polynucleotide capable of encoding a polypeptide and the polypeptide is not exclusive, since either the claimed polynucleotide or the claimed polypeptide can also be related to other polynucleotides or polypeptides, which are materially and chemically different from the claimed inventions. Therefore, the inventions of Groups 1-8 and the inventions of Groups 9-16, respectively, are patentably distinct products.

The inventions of Groups 1-8 and the inventions of Groups 9-16 have acquired a separate status in the art, as evidenced by their different classifications, and the search performed in

examining claims drawn to a polynucleotide is a different from the search performed in examining claims drawn to a polypeptide. Apart from the searching patent databases using the patent classification of the claimed subject matter, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, the search and considerations necessary in examining the merit of claims directed to the inventions of any of Groups 1-8 would not suffice to provide adequate information regarding the merit of the claims directed to the inventions of any of Groups 9-16, and vice versa, since the searches are not the same, nor are they one coextensive in scope and nature. Because different searches would have to be performed to examine the inventions of any of Groups 1-8 and the inventions of any of Groups 9-16, an examination of both would constitute a serious burden. Moreover, because the disclosed relationship between the polynucleotide and the polypeptide encoded by the polynucleotide is not absolute or exclusive of other relationships with different polynucleotides or polypeptides, the search of either group will likely provide information that is relevant to one but not the other; and as such, searching one in addition to the other would be unduly burdensome.

Since the inventions of any of Groups 1-8 and the inventions of any of Groups 9-16 are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

An antibody, such as an immunoglobulin G (IgG) molecule, typically comprises four polypeptides: two light chains and two heavy chains, each containing constant and variable regions, which interact with one another to form an antigen-binding domain comprised of amino acid residues in each chain. In contrast, claims polypeptides are disclosed as consisting of a single polypeptide chain; so the inventions of any of Groups CXXXVI-CLVII and the inventions of any of Groups CLXXX-CC are structurally distinct from one another. Thus, any relationship between an antibody and a polypeptide to which the antibody binds is codependent upon the structural (i.e., antigenic) information provided by the polypeptide, which is recognized as the antigenic determinant to which the antibody binds, and the selective binding nature of the antigen-binding domain of the antibody. However, a polypeptide comprises multiple antigenic

determinants and can thus elicit the production of multiple different antibodies, which recognize and bind structurally distinct portions (i.e., epitopes) of the polypeptide. Furthermore, an antibody is capable of recognizing and binding antigenic determinants that are shared by polypeptides, which are otherwise structurally and/or functionally distinct from the claimed polypeptide to which it binds (e.g., a human protein's mouse homolog, or a different member of a functionally related family of proteins). Consequently, the disclosed relationship between an antibody that binds a polypeptide and the polypeptide is not exclusive, since either the claimed antibody or the claimed polypeptide can also be related to other polypeptides or antibodies, respectively, which are materially and chemically different from the claimed inventions. Therefore, the inventions of any of Groups 9-16 and the inventions of any of Groups 33-40 are patentably distinct products.

Searching both the inventions of any of Groups 9-16 and the inventions of any of Groups 33-40 would be unduly burdensome, because the inventions have acquired a separate status in the arts, as evidenced by their separate classifications, and moreover because the necessary searches are not the same, nor are they coextensive in nature and scope with one another. A search of relevant sequence databases using the entire amino acid sequence of the polypeptide as query is necessary for the determination of the novelty and unobviousness of the polypeptide. However, such a search is not necessary, or sufficient to identify antibodies that bind the polypeptide, since antibodies that bind an epitope of the polypeptide may be known, even if the polypeptide is not (e.g., a anti-phosphotyrosine antibody binds a phosphotyrosine epitope, which is shared by numerous different proteins, and which would bind a novel tyrosine phosphorylated polypeptide). Accordingly, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, having to search both the inventions of any of Groups 9-16 and the inventions of any of Groups 33-40 would constitute a serious burden.

Since the inventions of any of Groups 9-16 and the inventions of any of Groups 33-40 are patentably distinct and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Groups 1-8 are nucleic acid molecules or polynucleotides, which are composed of polymers of nucleotides; whereas the inventions of Groups 33-40 are antibodies, which are composed of polymers of amino acids. Any relationship between a polynucleotide and a polypeptide is dependent upon the information provided by the nucleotide sequence of the polynucleotide, as it corresponds to an "open reading frame" encoding the amino acid sequence of the polypeptide. However, the claimed polynucleotide does not encode a polypeptide chain of the claimed antibody; and the claimed antibody cannot be encoded by the claimed polynucleotide. Therefore, the inventions of any of Groups 1-8 and the inventions of any of Groups 33-40 are patentably distinct products.

Searching both the inventions of any of Groups 1-8 and the inventions of any of Groups 33-40 would be unduly burdensome, because the inventions have acquired a separate status in the arts, as evidenced by their separate classifications, and moreover because the necessary searches are not the same, nor are they coextensive in nature and scope with one another. Therefore, having to search both the inventions of any of Groups 1-8 and the inventions of any of Groups 33-40 would constitute a serious burden.

Since the inventions of any of Groups 1-8 and the inventions of any of Groups 33-40 are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Groups 1-8 are patentably distinct, each from the others, because each is a nucleic acid molecule, or composition thereof, comprising a distinct polynucleotide sequence that is disclosed as encoding a different protein comprising a distinct amino acid sequence.

Because of the these differences, the search necessary to examine claims directed to any of the inventions of Groups 1-8 is not the same, nor is it coextensive with the search necessary to examine claims directed to any of the others. Accordingly, a separate and different search would have to be performed to examine claims directed to any one of these groups of inventions. Therefore, the examination of more than one of the inventions would constitute a serious burden.

Since the inventions of Groups 1-8 are patentably distinct from the others and because the examination of more than one could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Groups 9-16 are patentably distinct, each from the others, because each is a protein, or a composition thereof, comprising a distinct amino acid sequence, which is encoded by a nucleic acid molecule having a distinct polynucleotide sequence.

Because of the these differences, the search necessary to examine claims directed to any of the inventions of Groups 9-16 is not the same, nor is it coextensive with the search necessary to examine claims directed to any of the others. Accordingly, a separate and different search would have to be performed to examine claims directed to any one of these groups of inventions. Therefore, the examination of more than one of the inventions would constitute a serious burden.

Since the inventions of Groups 9-16 are patentably distinct from the others and because the examination of more than one could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Groups 33-40 are patentably distinct, each from the others, because each is an antibody that binds a protein comprising a distinct amino acid sequence, which is encoded by a nucleic acid molecule having a distinct polynucleotide sequence.

Because of the these differences, the search necessary to examine claims directed to any of the inventions of Groups 33-40 is not the same, nor is it coextensive with the search necessary to examine claims directed to any of the others. Accordingly, a separate and different search would have to be performed to examine claims directed to any one of these groups of inventions. Therefore, the examination of more than one of the inventions would constitute a serious burden.

Since the inventions of Groups 33-40 are patentably distinct from the others and because the examination of more than one could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Groups 17-32 and 41-50 are unrelated, or are otherwise patentably distinct, each from the other, for the following reasons:

The inventions of Groups 17-24 and 25-32 are methods for modulating tumor cell proliferation, whereas the inventions of Groups 41-48 are methods for detecting the presence of a protein in a sample, the inventions of Group 49 are methods for detecting the presence of a

nucleic acid molecule in a sample, and the inventions of Group 50 are methods for assessing the risk of metastasis or prognosis.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, and different effects. See MPEP §§ 806.04 and 808.01. The instant specification does not appear to disclose that any of the inventions of Groups 17-24 and 25-32, any of the inventions of Groups 41-48, the inventions of Group 49, and the inventions of Group 50 are useable together. Therefore, because the inventions of Groups 17-24 and 25-32, the inventions of Groups 41-48, the inventions of Group 49, and the inventions of Group 50 have different purposes, the inventions appear unrelated.

If not unrelated, the inventions of Groups 17-24 and 25-32, the inventions of Groups 41-48, the inventions of Group 49, and the inventions of Group 50 are patentably distinct, each from the others, for the following reasons:

Again, the inventions of Groups 17-24 and 25-32, the inventions of Groups 41-48, the inventions of Group 49, and the inventions of Group 50 have different purposes or objectives.

In addition, the inventions of Groups 17-24 and 25-32, the inventions of Groups 41-48, the inventions of Group 49, and the inventions of Group 50 are materially different processes comprising different process steps. For example, the inventions of Groups 41-48, which are processes for detecting the presence of a protein, comprise contacting a sample with an antibody; in contrast, the inventions of Group 49, which are processes for detecting the presence of a nucleic acid molecule, comprise contacting a sample with a nucleic acid probe.

As the inventions of the different groups have different purposes or objectives, they necessarily involve the measurement of different endpoints and the establishment of different correlations, and as such they necessarily have different criteria for success. For these reasons, any of the inventions of Groups 17-24 and 25-32, the inventions of Groups 41-48, the inventions of Group 49, and the inventions of Group 50 are patentably distinct from the others.

Furthermore, although the inventions of Groups 17-24 and the inventions of Groups 25-32 are have the same objective, as they are each processes for modulating tumor cell proliferation, the inventions of Groups 17-24 comprise administering a nucleic acid molecule, whereas the inventions of Groups 25-32 comprise administering a protein. Accordingly, the

inventions of Groups 17-24 and the inventions of Groups 25-32 are materially different processes, which achieve the claimed effect by a different mode of operation.

Because the inventions of Groups 17-24 and 25-32, the inventions of Groups 41-48, the inventions of Group 49, and the inventions of Group 50 are distinct for these reasons, the search required to examine claims directed to any one of these inventions is not the same, nor is it coextensive with the search required to examine claims directed to any other. Furthermore, the inventions of Groups 17-24 and 25-32, the inventions of Groups 41-48, the inventions of Group 49, and the inventions of Group 50 have acquired a separate status in the art, as evidenced by their different classifications and/or art-recognized divergence in subject matter. Because different searches would have to be performed to examine claims directed to the inventions of Groups 17-24 and 25-32, the inventions of Groups 41-48, the inventions of Group 49, and the inventions of Group 50, an examination of more than one would constitute a serious burden.

Since the inventions of Groups 17-24 and 25-32, the inventions of Groups 41-48, the inventions of Group 49, and the inventions of Group 50 have been shown to be patentably distinct, each from the others, and because the examination of more than one could not be made without serious burden, it is proper to restrict each from the other. See MPEP § 803.

5. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, searching more than one invention encompassed by the claim would constitute a serious burden; therefore, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D., whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1643

slr
September 19, 2006